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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/821,624	04/09/2004	Michael John Dunkley	0197.00	8935
21968	7590	01/11/2006		
NEKTAR THERAPEUTICS 150 INDUSTRIAL ROAD SAN CARLOS, CA 94070			EXAMINER ALI, SHUMAYA B	
			ART UNIT	PAPER NUMBER
			3743	
DATE MAILED: 01/11/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary	Application No. 10/821,624	Applicant(s) DUNKLEY ET AL.	
	Examiner Shumaya B. Ali	Art Unit 3743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 November 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-34 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12, 14-20, 34 and 37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 13 and 21-26 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input checked="" type="checkbox"/> Other: <u>detailed action</u> . |

DETAILED ACTION

Response to Arguments

1. Applicant's arguments with respect to claims **1-12,14-20,27-34** have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-12,14-20,27-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ohki et al.

US Patent 5,921,236 in view of Gottenauer et al. US Patent No. 5,881,719

2. **As to claim 1, Ohki et al. disclose** an aerosolization apparatus (see fig.1 reference object 1) comprising: a housing (fig.2 inside the reference object 15) defining a chamber (fig.2 reference object 12) having one or more air inlets (fig.2 reference object 5), the chamber being sized to receive a capsule (see fig.4 reference object K) which contains an aerosolizable pharmaceutical formulation (in the form of powder, col.1 line 14); a puncturing mechanism (fig.2 reference object 27) within the housing, the puncturing mechanism comprising an alignment guide (fig.2 reference object 8) and a puncture member (fig.2 reference object 27A), wherein the alignment guide comprises a surface (fig.5 reference object 8A) adapted to contact (fig.5 seems to depict object 8A has a flat surface where a capsule contacts) the

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capsule while the puncture member is advanced into the capsule to create an opening (col.3 lines 14-15) in the capsule, and wherein at least a portion of the surface is sloped at an angle (fig.5 reference object 8 makes perpendicular angle to a base surface 8A), **however do not disclose the angle is less than 55 degrees relative to the longitudinal axis of the capsule. As to the limitation, Gottenauer et al. teaches an inhaler in figures 3,4, and 6 for administering medicaments from blister pack with at least one plunger 10 with a curved surface adapted to the shape of the blister cavities. The concave curvature of the engaging plunger surface adapted to the convexly curved shape of the blister cavities prevents the medicament from being compressed inside the cavities when they are pressed out and thus from no longer being able to be dispersed sufficiently in the air flow (see col.2 lines 58-67, col.3 lines 1-2). Therefore, it would have been obvious to one of ordinary skills in the art at the time the invention was made to modify the inhaler of Ohki in view of Gottenauer et al. in order to provide the guide with curved surface which can be angled less than 55 degrees for the purposes of puncturing blister tablets or capsule with precision so that dispersion of the medicament is successfully obtained.**

3. **As to claim 2, Ohki et al. do not disclose an aerosolization apparatus according to claim 1 wherein the surface is sloped at an angle, which is from 35 to 55 degrees relative to the longitudinal axis of the capsule. As to claim 3, Ohki et al. do not disclose an aerosolization apparatus according to claim 1 wherein the surface is sloped at an angle, which is from 37 to 50 degrees relative to the longitudinal axis of the capsule. As to claim 4, Ohki et al. do not disclose an aerosolization apparatus according to claim 1 wherein the surface is sloped at an angle of about 45 degrees relative to the longitudinal axis of the capsule. However do not disclose the angle is less than 55 degrees relative to the longitudinal axis of the capsule. As to the limitation, Gottenauer et al. teaches an inhaler in figures 3,4, and 6 for**

administering medicaments from blister pack with at least one plunger 10 with a curved surface adapted to the shape of the blister cavities. The concave curvature of the engaging plunger surface adapted to the convexly curved shape of the blister cavities prevents the medicament from being compressed inside the cavities when they are pressed out and thus from no longer being able to be dispersed sufficiently in the air flow (see col.2 lines 58-67, col.3 lines 1-2). Therefore, it would have been obvious to one of ordinary skills in the art at the time the invention was made to modify the inhaler of Ohki in view of Gottenauer et al. in order to provide the guide with curved surface which can be angled as claimed for the purposes of puncturing blister tablets or capsule with precision so that dispersion of the medicament is successfully obtained.

4. As to claim 5, Ohki et al. disclose an aerosolization apparatus according to claim 1 wherein the puncturing mechanism is at least partially within the chamber (fig.2 seems to depict a puncturing mechanism comprises a pin (27) situated within a chamber).

5. As to claim 6, Ohki et al. disclose an aerosolization apparatus according to claim 1 wherein surface comprises a passageway (fig.2 reference object 8C) and wherein the puncture member slides (the puncture member slides when a force is delivered by reference object 15) within the passageway.

6. As to claim 7, Ohki et al. do not disclose an aerosolization apparatus according to claim 1 wherein the wherein the surface is sloped at an angle which less than 55 degrees relative to the longitudinal axis of the puncture member. As to claim 8, Ohki et al. do not disclose an aerosolization apparatus according to claim 1 wherein the wherein the surface is sloped at an angle which less than 55 degrees relative to the longitudinal axis of the chamber. As to claim 9, Ohki et al. do not disclose an aerosolization apparatus according to claim 1 wherein the wherein the surface is sloped at an angle which less than 55 degrees relative to an inhalation direction. However do not disclose the angle is less than

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55 degrees relative to the longitudinal axis of the capsule. As to the limitation, Gottenauer et al. teaches an inhaler in figures 3,4, and 6 for administering medicaments from blister pack with at least one plunger 10 with a curved surface adapted to the shape of the blister cavities. The concave curvature of the engaging plunger surface adapted to the convexly curved shape of the blister cavities prevents the medicament from being compressed inside the cavities when they are pressed out and thus from no longer being able to be dispersed sufficiently in the air flow (see col.2 lines 58-67, col.3 lines 1-2). Therefore, it would have been obvious to one of ordinary skills in the art at the time the invention was made to modify the inhaler of Ohki in view of Gottenauer et al. in order to provide the guide with curved surface which can be angled less than 55 degrees for the purposes of puncturing blister tablets or capsule with precision so that dispersion of the medicament is successfully obtained.

7. As to claim 10, Ohki et al. disclose an aerosolization apparatus according to claim 1 wherein the surface is moveable (col.2 lines 29-31) within the chamber.

8. As to claim 11, Ohki et al. do not disclose an aerosolization apparatus according to claim 10 wherein the wherein the surface is sloped at an angle which less than 55 degrees relative to the direction of movement of the surface, however as discussed above, figure 2 depicts an inhalation device at its longitudinal axis, and the surface makes an angle relative to that axis. Since the surface is movable as disclosed by Ohki et al., it would have been obvious to one of ordinary skills in the art to recognize that the angle is also movable relative to the direction of the movement of the surface as well.

9. As to claim 13, Ohki et al. disclose an aerosolization apparatus according to claim 1 wherein the surface comprises one or more protrusions (see fig.5 reference object 8D) and wherein the one or more

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protrusions are adapted to (fig.5 seems to depict a capsule is situated between the two protrusion members) contact the capsule.

10. As to claim 14, Ohki et al. do not disclose an aerosolization apparatus according to claim 1 wherein the end section is removably connected to the housing and wherein the end section may be removed from the housing to provide access to the chamber. **However, Ohki's figures depict that a capsule is positioned within a chamber inside an inhaler. By comparing figure 1 to any of the other figures it would have been obvious to one of ordinary skills in that art that end section of figure 1 has to be removed in order to provide an access to the chamber for the purposes of positioning a capsule inside the chamber.**

11. As to claim 15, Ohki et al. disclose an aerosolization apparatus according to claim 1 wherein the puncture mechanism comprises a pair of puncture members (fig.5 reference objects 27 and 28).

12. As to claim 16, Ohki et al. disclose an aerosolization apparatus according to claim 1 wherein the puncture member is adapted to (each puncture member is designed to puncture one hole at one end of the capsule, see col.2 lines 45-58) puncture only one end of the capsule.

13. As to claim 17, Ohki et al. disclose an aerosolization apparatus according to claim 1 wherein the chamber is elongated (fig.2 reference object 12 is considered elongated) and wherein the capsule is received lengthwise (fig.5 seems to depict a capsule is situated in lengthwise direction in a chamber) within the elongated chamber.

14. As to claim 18, Ohki et al. disclose Ohki et al. disclose an aerosolization apparatus according to claim 1 wherein the width of the chamber is less than the length of the capsule (fig.2 seems to depict a capsule is situated in a chamber where the chamber has a width less than the length of the capsule).

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15. **As to claim 18, Ohki et al. disclose** an aerosolization apparatus according to claim 1 wherein the inlet is shaped to create a swirling (the airflow causes the powder to be aerosolized, therefore the flow is considered swirling air-flow) airflow within the chamber.

16. **As to claim 19, Ohki et al. disclose** an aerosolization apparatus comprising: a housing (fig.2 inside the reference object 15) defining a chamber (fig.2 reference object 12) having one or more air inlets (fig.2 reference object 5), the chamber being sized to receive a capsule (fig.5 reference object K) which contains an aerosolizable pharmaceutical formulation (in the form of powder, col.1 line 14); a puncturing mechanism (fig.2 reference object 27) within the housing, the puncturing mechanism comprising an alignment guide (fig.2 reference object 8) and a puncture member (fig.2 reference object 27), wherein the alignment guide comprises a surface (fig.2 reference object) adapted to contact (fig.5 seems to depict object 8A has a flat surface where a capsule contacts) the capsule while the puncture member is advanced into the capsule to create an opening (col.3 lines 14-15) in the capsule, and wherein the surface comprises one or more protrusions (fig.5 reference object 8D) for contacting the capsule; and an end section (fig.2 reference object 20) associated with the housing, the end section sized and shaped to be received in a user's mouth or nose (Ohki discloses a nasal inhaler, see col.1 lines 6-8) so that the user may inhale through the end section to inhale aerosolized pharmaceutical formulation that has exited the capsule through the opening created in the capsule.

17. **As to claim 20, Ohki et al. disclose** an aerosolization apparatus according to claim 20 wherein surface comprises a passageway (fig.2 reference object 8C) and wherein the puncture member slides (the puncture member slides when a force is delivered by reference object 15) within the passageway.

18. **As to claim 21, Ohki et al. disclose** an aerosolization apparatus according to claim 20 wherein the inlet is shaped to create a swirling (inlet has long narrow opening, upon actuation air forcing out of the

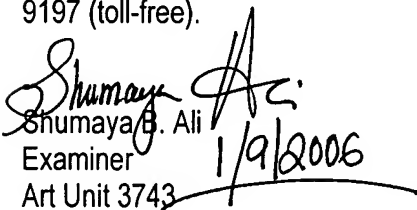
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narrow opening into a larger chamber will create swirling of air-flow, and the term "spray" used throughout Ohki's disclosure is considered an equivalent of swirling air-flow, see also col.2 lines 55-65) airflow within the chamber.

19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Shumaya B. Ali** whose telephone number is **571-272-6088**. The examiner can normally be reached on M-F 8:30 am-4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Henry Bennett** can be reached on **571-272-4791**. The fax phone number for the organization where this application or proceeding is assigned is 571-273-6088.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


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Art Unit 3743
1/9/2006


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